## **Environmental Protection Agency**

Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

- (2) Newer notices. For MCANs submitted on or after April 6, 2010, EPA will accept notices of commencement only if submitted in accordance with this paragraph:
- (i) Notices of commencement may be submitted on paper on or before April 6, 2011. All paper-based notices of commencement must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper notices of commencement must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M). Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.
- (ii) Notices of commencement may be submitted as electronic files on optical disc on or before April 6, 2012. All notices of commencement submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices of commencement must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.
- (iii) Notices of commencement may be submitted electronically to EPA via CDX on or after April 6, 2010. After April 6, 2012 all notices of commencement must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN reporting software. See 40 CFR 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

## Subpart E—Exemptions for Research and Development Activities

## §725.200 Scope and purpose.

- (a) This subpart describes exemptions from the reporting requirements under subpart D of this part for research and development activities involving microorganisms.
- (b) In lieu of complying with subpart D of this part, persons described in §725.205 may submit a TSCA Experimental Release Application (TERA) for research and development activities involving microorganisms or otherwise comply with this subpart.
- (c) Exemptions from part 725 are provided at §§ 725.232, 725.234, and 725.238.
- (d) Submission requirements specific for TERAs are described at §725.250.
- (e) Data requirements for TERAs are set forth in §§ 725.255 and 725.260.
- (f) EPA review procedures specific for TERAs are set forth in §§ 725.270 and 725.288.
- (g) Subparts A through C of this part apply to any submission under this subpart.

## § 725.205 Persons who may report under this subpart.

- (a) Commercial research and development activities involving new microorganisms or significant new uses of microorganisms are subject to reporting under this part unless they qualify for an exemption under this part.
- (b) Commercial purposes for research and development means that the activities are conducted with the purpose of obtaining an immediate or eventual commercial advantage for the researcher and would include:
- (1) All research and development activities which are funded directly, in whole or in part, by a commercial entity regardless of who is actually conducting the research. Indications that the research and development activities are funded directly, in whole or in part, may include, but are not limited to:
- (i) Situations in which a commercial entity contracts directly with a university or researcher; or
- (ii) Situations in which a commercial entity gives a conditional grant where the commercial entity holds patent